

II. RESPONSE TO OFFICE ACTION

A. Status of the Claims

Claims 1-20 and 26-82 were pending in the case at the time of the Action, with claims 51-68, 78, and 79 having been withdrawn from consideration as being drawn to a non-elected invention. Claims 1 and 35 have been amended in the Amendment set forth herein. No claims have been canceled. New claims 83-90 have been added.

Support for the amendment of claim 1 and new claims 87-90 to recite a particular range of molar ratios can be found generally throughout the specification, such as on page 4, lines 27-31. Support for the remaining new claims can be found generally throughout the specification, such as on page 10, lines 20-29, Table 1 on pages 11-14, page 5, lines 7-19 (claims 83-86). Therefore, claims 1-20 and 26-90 are currently pending in the case.

B. Teleconference with Examiner

On April 28, 2006, Applicants' representatives, Steven Highlander and Michael Samardzija, had a teleconference with Examiner Jastrzab, to discuss the Office Action. Agreement was not reached, but Applicants believe that the issues for further prosecution were clarified.

C. The Rejections Under 35 U.S.C. §112, Second Paragraph, Are Overcome

Claim 35 is rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. In particular, the phrase "the composition" in claim 35 is said to lack antecedent basis. Applicants point out that claim 1 has been amended to recite "basic reagent bound to a dye" instead of "composition," and that there is antecedent basis for "basic reagent bound to a dye." Therefore, this rejection has been overcome.

D. The Rejections Under 35 U.S.C. §102(e) Are Overcome

1. Rejections Based on Houze *et al.*

Claims 1-2, 4-5, 12, 14, 28-32, 34, 36-43, 69-71, and 80-82 are rejected under 35 U.S.C. §102(e) as being anticipated by Houze *et al.* Houze *et al.* is said to teach a composition comprising a basic reagent (guanidines, such as alexidine and chlorohexidine) and a dye (gentian violet). Applicants respectfully traverse this rejection and respond as follows.

However, Houze *et al.* is not available as prior art. In accordance with 37 C.F.R. § 1.131, Applicants herein submit a declaration of the inventors of the instant patent application (Appendix 1; hereinafter, “the Declaration”) setting forth that the inventors conceived of the invention prior to the priority date of Houze *et al.* and were diligent in reducing their invention to practice by filing a U.S. provisional patent application.

As an initial matter, Applicants point out that Houze *et al.* claims priority to Continuation-in-part application No. 09/161,312 (filed Sep. 28, 1998; now U.S. Patent 6,562,363), and that Applicants find no disclosure in U.S.S.N. 09/161,312 pertaining to gentian violet. Therefore, as to any disclosure pertaining to a composition comprising a dye, Houze *et al.* is only entitled to a priority date of May 13, 2003, its filing date.

The Declaration sets forth facts that prior to September 25, 1998, the inventors conceived of the idea of preparing compositions that include a basic reagent and a dye, and methods for disinfecting or sterilizing a surface that involve applying to the surface a composition that includes a basic reagent and a dye. Declaration, paragraph 2.

The inventors have included Exhibits 1-6 in their Declaration, which are copies of literature searches that were conducted prior to September 25, 1998, to assess what was known in the literature pertaining to certain anti-infective agents, two of which are chlorhexidine and berberine. Declaration, paragraph 3, and Exhibits 1-6.

Further, as set forth in the Declaration, the inventors were diligent from prior to September 25, 1998 until they filed their provisional application in conducting studies to prepare compositions of their invention and evaluate their effectiveness as antimicrobial compositions. Declaration, paragraph 4. As evidence of diligence, the inventors have provided Exhibits 7-16, which include additional literature searches for basic reagents and dyes. Declaration, paragraph 5, Exhibits 7-16. The inventors have also provided a summary of experiments performed after September 25, 1998, but prior to January 12, 2001, which showed the efficacy of combining various basic reagents and dyes. Declaration, paragraph 6, Exhibit 16. In this regard, references to “Gendine” are to a combination of Gentian violet (also referred to as “Gv”) and chlorhexidine), and reference to “PCMX” is to chloroxylenol [p-chloro-m-xylenol; 4-chloro-3,5-dimethylxylenol]. Declaration, paragraph 7.

Therefore, in view of the above, Applicants have demonstrated that in accordance with 37 C.F.R. §1.131(b), Houze *et al.* is not prior art. Therefore, Applicants respectfully request that this rejection is overcome.

2. Rejections Based on Rosenberg (U.S. Patent 6,465,521)

Claims 1, 6, 9-10, and 12 have been rejected under 35 U.S.C. §102(e) as being anticipated by Rosenberg (U.S. Patent 6,465,521). Applicants respectfully traverse this rejection and respond as follows.

a) Rosenberg Does Not Anticipate Claims 1, 6, 9-10, and 12

Rosenberg does not anticipate the claimed invention because it does not expressly or inherently disclose each limitation of the claimed invention. “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). Rosenberg fails to expressly or inherently disclose any

composition wherein the molar ratio of dye to basic reagent is 1:1 – 1:99 or the molar ratio of basic reagent to dye is 1:1 -1:99. Therefore, it is respectfully requested that this rejection should be withdrawn.

b) Rosenberg Does Not Anticipate the New Claims

Applicants point out that new claims 83-90 have been added, none of which are anticipated by Rosenberg. Claims 83-86 recite particular dyes, and claims 87-90 recite particular molar ratios of dye to basic reagent. Applicants find no disclosure in Rosenberg pertaining to any of the dyes set forth in claims 83-86. Nor do Applicants identify any composition in Rosenberg *et al.* that includes the range of molar ratios recited in claims 87-90. Therefore, Rosenberg does not anticipate these claims.

c) Rosenberg, if Cited in an Obviousness Rejection, Would Not Render the Claimed Invention Obvious

Applicants point out that even if Rosenberg were cited in a rejection under 35 U.S.C. §103(a), there would be no *prima facie* case of obviousness.

In order to establish a *prima facie* case of obviousness, three basic criteria must be met: (1) the prior art reference (or references when combined) must teach or suggest all the claim limitations; (2) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; (3) there must be a reasonable expectation of success. *Manual of Patent Examining Procedure* § 2142. See also *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q. 2d 1438 (Fed Cir. 1991). It is important to note that all three elements must be shown to establish a *prima facie* case of obviousness. Thus, if one element is missing, a *prima facie* case of obviousness does not exist.

Applicants point out that as to claim 1 and claims that depend from claim 1, Rosenberg *et al.* does not teach or suggest the recited molar ratios of dye to basic reagent. Rosenberg provides no teaching or suggestion that would lead one of ordinary skill in the art to provide for such molar ratios. Rosenberg teaches use of dyes for the purpose of providing color, rather than conferring any antiseptic property. Therefore, the molar ratios of dye:basic reagent in the compositions set forth in Rosenberg are substantially different, *i.e.*, on the order of 1:650 – 1:4,400. Rosenberg would thus actually teach away from the molar ratios of dye:basic reagent set forth in claim 1.

Even if the Examiner argues that a *prima facie* case of obviousness has been made, Applicants would still overcome any obviousness rejection because Applicants have set forth in a Declaration of Dr. Isaam Raad (attached as Appendix 2) as evidence that compositions of basic reagents and dyes of the present invention provide antiseptic efficacy that is surprisingly and unexpectedly superior than either agent alone. In particular, the combination of a basic reagent and a dye has antiseptic ability as a mouthwash, coating of a glove, or coating of a catheter, that is more than additive compared to either dye alone or basic reagent alone. Pages 1-3 of Exhibit 1 of Appendix 2 describes studies reporting the antiseptic efficacy of gloves coated with various combinations of a dye and a basic reagent. All compositions evaluated that included a dye and basic reagent showed excellent efficacy as an antiseptic coating of gloves, with zones of inhibition being comparable with no leaching. Appendix 2, paragraph 3, and Exhibit 1. Studies were conducted evaluating the antiseptic efficacy of central venous catheters coated with chlorhexidine in combination with one of the selected dye from a group of Erythrosin B, Sudan III, Fast Green, Brilliant Green, Solvent Green 3, Quinoline Yellow, Indigo Carmine, Gentian Violet and Tartrazine. Exhibit 1, pages 6-8. Appendix 2, paragraph 3, and Exhibit 1. These

results clearly establish that the combination of a dye and basic reagent exhibits surprising and unexpected superiority as an antiseptic than either the dye alone or the basic reagent, and that antiseptic efficacy of the composition of a dye and basic reagent was more than additive of either the dye alone or the basic reagent alone. Appendix 2, paragraph 6.

3. Rejections Based on Harper *et al.*

Claims 1, 8, 12-13, 74, and 80 have been rejected under 35 U.S.C. §102(e) as being anticipated by Harper *et al.* (U.S. Patent Pub. No. 2005/0049306). Applicants respectfully traverse and respond as follows.

In view of the Declaration of Inventors under 37 C.F.R. §1.131 discussed above, Harper *et al.* is not available as prior art. The Declaration sets forth that the inventors conceived of the invention prior to the priority date of Harper *et al.* and were diligent in reducing their invention to practice until the filing of their provisional patent application. The previous discussion pertaining to the Declaration of the inventors is incorporated into this section.

Therefore, in view of the above, it is respectfully submitted that this rejection is overcome.

4. Rejections Based on Parikh *et al.*

Claims 1 and 26-27 are rejected under 35 U.S.C. §102(a) or (e) as being anticipated by Parikh *et al.* (U.S. Patent 6,123,926). Applicants respectfully traverse and respond as follows.

In view of the Declaration of Inventors under 37 C.F.R. §1.131 discussed above, Parikh *et al.* is not available as prior art. The Declaration sets forth that the inventors conceived of the invention prior to the priority date of Parikh *et al.* and were diligent in reducing their invention to practice until the filing of their provisional patent application. The previous discussion pertaining to the Declaration of the inventors is incorporated into this section.

Therefore, in view of the above, it is respectfully submitted that this rejection is overcome.

5. Rejections Based on Zhuang *et al.*

Claims 1 and 80 have been rejected under 35 U.S.C. §102(e) as being anticipated by Zhuang *et al.* (U.S. Patent Pub. No. 2004/0132699). Applicants respectfully traverse and respond as follows.

In view of the Declaration of Inventors under 37 C.F.R. §1.131 discussed above, Zhuang *et al.* is not available as prior art. The Declaration sets forth that the inventors conceived of the invention prior to the priority date of Zhuang *et al.* and were diligent in reducing their invention to practice until the filing of their provisional patent application. The previous discussion pertaining to the Declaration of the inventors is incorporated into this section.

Therefore, in view of the above, it is respectfully submitted that this rejection is overcome.

E. The Rejections Under 35 U.S.C. §103(a) Are Overcome

1. Rejections Based on Harper *et al.*

Claims 75-77 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Harper *et al.*, as applied to claims 1, 8, 12-13, 74, and 80 above. Applicants respectfully traverse this rejection, and respond as follows.

For the reasons discussed above, the discussion of which is incorporated into this section, Harper *et al.* is not available as prior art. The inventors have demonstrated conception before the priority date of Harper *et al.*, and were diligent in conducting studies to prepare compositions of their invention and evaluate their effectiveness as antimicrobial compositions from prior to September 25, 1998, until they filed their provisional application.

Even if Harper *et al.* was available as prior art, which is not the case, Applicants would still overcome any obviousness rejection because Applicants have set forth in a Declaration of Dr. Isaam Raad (attached as Appendix 2) as evidence that compositions of basic reagents and dyes of the present invention provide antiseptic efficacy that is surprisingly and unexpectedly superior than either agent alone. See, e.g., pages 1-4 of Exhibit 1 of Declaration of Dr. Raad, particularly page 4 of Exhibit 1 setting forth synergism of chlorhexidine and brilliant green compared to saline control.

Therefore, in view of the above, this rejection has been overcome.

2. Rejections Based on Harper *et al.* and further in view of Kirk-Othmer Encyclopedia of Chemical Technology

Claims 6, 7, 9, 11, and 15-20 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Harper *et al.* as applied to claim 1 above, and further in view of Kirk-Othmer Encyclopedia of Chemical Technology. Applicants respectfully traverse, and respond as follows.

For the reasons discussed above, the discussion of which is incorporated into this section, Harper *et al.* is not available as prior art in view of the Declaration of inventors under 37 C.F.R. §1.131. The inventors have demonstrated conception before the priority date of Harper *et al.*, and were diligent in conducting studies to prepare compositions of their invention and evaluate their effectiveness as antimicrobial compositions from prior to September 25, 1998, until they filed their provisional application. Therefore, because Harper *et al.* is not available as prior art, and because Kirk-Othmer does not teach each limitation of the claimed invention, this rejection is overcome.

For the reasons discussed above, even if Harper et al. were available as prior art, there would still be no *prima facie* case of obviousness. The compositions of the present invention demonstrate surprising and unexpected antiseptic efficacy compared to either agent alone. This finding is sufficient to rebut any *prima facie* case of obviousness.

3. Rejections Based on Houze et al.

Claims 3, 33, and 44-50 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Houze et al. Applicants respectfully traverse, and respond as follows.

For the reasons discussed above, the discussion of which is incorporated into this section, Houze et al. is not available as prior art in view of the Declaration of inventors under 37 C.F.R. §1.131. The inventors have demonstrated conception before the priority date of Houze et al., and were diligent in conducting studies to prepare compositions of their invention and evaluate their effectiveness as antimicrobial compositions from prior to September 25, 1998, until they filed their provisional application. Therefore, this rejection is overcome.

Even if the Examiner argues that a *prima facie* case of obviousness has been made, Applicants would still overcome any obviousness rejection because Applicants have set forth in a Declaration of Dr. Isaam Raad (attached as Appendix 2) as evidence that compositions of basic reagents and dyes of the present invention provide antiseptic efficacy that is surprisingly and unexpectedly superior than either agent alone. In particular, the combination of a basic reagent and a dye has antiseptic ability as a mouthwash, coating of a glove, or coating of a catheter, that is more than additive compared to either dye alone or basic reagent alone.

4. Rejections Based on Houze *et al.* and Further in View of Beerse *et al.*

Claims 72 and 73 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Houze *et al.*, as applied to claim 69 above, and further in view of Beerse *et al.* Applicants respectfully traverse, and respond as follows.

For the reasons discussed above, the discussion of which is incorporated into this section, Houze *et al.* is not available as prior art in view of the Declaration of inventors under 37 C.F.R. §1.131. The inventors have demonstrated conception before the priority date of Houze *et al.*, and were diligent in conducting studies to prepare compositions of their invention and evaluate their effectiveness as antimicrobial compositions from prior to September 25, 1998, until they filed their provisional application.

Therefore, because Houze *et al.* is not available as prior art, and because Beerse does not teach or suggest each limitation of the claimed invention, this rejection is overcome.

Even if the Examiner argues that a *prima facie* case of obviousness has been made, Applicants would still overcome any obviousness rejection because Applicants have set forth in a Declaration of Dr. Isaam Raad (attached as Appendix 2) as evidence that compositions of basic reagents and dyes of the present invention provide antiseptic efficacy that is surprisingly and unexpectedly superior than either agent alone. In particular, the combination of a basic reagent and a dye has antiseptic ability as a mouthwash, coating of a glove, or coating of a catheter, that is more than additive compared to either dye alone or basic reagent alone.

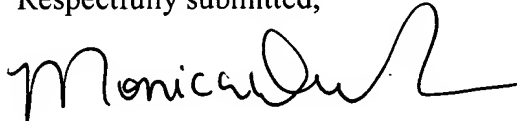
In view of the above, it is submitted that each of the pending claims is in condition for allowance, and an early indication to that effect is earnestly solicited.

III. REQUEST FOR EXTENSION OF TIME

Pursuant to 37 C.F.R. § 1.136(a), Applicant petitions for an extension of time of one month to and including May 11, 2006, in which to respond to the Office Action dated January 11, 2006. Pursuant to 37 C.F.R. § 1.17, a check is enclosed, which is the process fee for a one-month extension of time. If the check is inadvertently omitted, or should any additional fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason relating to the enclosed materials, or should an overpayment be included herein, the Commissioner is authorized to deduct or credit said fees from or to Fulbright & Jaworski Deposit Account No. 50-1212/UTSC:669US.

The Examiner is invited to contact the undersigned attorney at (512) 536-5639 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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APPENDIX 1